In the United States Court of Federal Claims

No. 17-936V
Filed Under Seal: March 17, 2020
Reissued: April 27, 2020[*]

MARY ORLOSKI, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	)	National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa–1 to –34; Acute Disseminated Encephalomyelitis; *Althen* Prong One; *Althen* Prong Two; *Althen* Prong Three.

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MEMORANDUM OPINION AND ORDER

GRIGGSBY, Judge

I. INTRODUCTION

Petitioner, Mary Orloski, seeks review of the October 31, 2019, decision of the special master (the "October 31, 2019, Decision") denying her claim for compensation under the National Childhood Vaccine Injury Act (the "Vaccine Act"), 42 U.S.C. § 300aa–1 to –34. Petitioner alleges that the influenza vaccine, and/or the tetanus-diphtheria-acellular-pertussis

[*] This Memorandum Opinion and Order was originally filed under seal on March 17, 2020. ECF No. 53. The parties were given an opportunity to advise the Court of their views with respect to what information, if any, should be redacted from the Memorandum Opinion and Order. On April 27, 2020, petitioner filed a joint status report on behalf of the parties stating that the parties had no redactions to the Memorandum Opinion and Order. ECF No. 56. And so, the Court is reissuing its Memorandum Opinion and Order, dated March 17, 2020, as the public opinion.

("Tdap") vaccine, caused her to develop acute disseminated encephalomyelitis ("ADEM"). For the reasons set forth below, the Court **DENIES** petitioner's motion for review and **SUSTAINS** the decision of the special master.

II. FACTUAL AND PROCEDURAL BACKGROUND[1]

A. Factual Background

In this Vaccine Act matter, petitioner alleges that the influenza vaccine that she received on October 23, 2014, and/or the Tdap vaccine that she received on November 18, 2015, caused her to develop ADEM. *See generally* Pet'r Pet. On October 31, 2019, the special master denied petitioner's claim for compensation under the Vaccine Act. *See generally* October 31, 2019, Decision.

1. Petitioner's Medical History

Petitioner's medical history is discussed in detail in the special master's October 31, 2019, Decision and is briefly summarized here. October 31, 2019, Decision at 3-8.

Petitioner received the influenza vaccine on October 23, 2014, at approximately 7:00 a.m. Pet'r Ex. 1(c) at 00036. Later that day, petitioner was treated at the emergency room for visual disturbances in both eyes that had presented after receiving the influenza vaccine. *Id.*

At the time, petitioner stated her belief that she was suffering from an allergic reaction to the vaccination. *Id.* But, petitioner's treating physician assistant disagreed and directed petitioner to follow up with her primary care physician. *Id.* at 000036-37.

On December 5, 2014, petitioner presented to her primary care physician, Charles Burger, M.D., to discuss her post-traumatic distress disorder and related symptoms that she believed had been triggered by an allergic reaction to the influenza vaccine. Pet'r Ex. 1(f) at 000003. During this visit, Dr. Burger referred petitioner to a psychiatrist, David Breer, M.D., without prescribing any medication. *Id.*

[1] The facts recounted in this Memorandum Opinion and Order are taken from the petitioner's petition ("Pet'r Pet."); petitioner's motion for review ("Pet'r Mot. for Rev.") and memorandum in support thereof ("Pet'r Mem."); petitioner's exhibits ("Pet'r Ex."); the Secretary's exhibits ("Resp't Ex."); and the Special Master's October 31, 2019, Decision ("October 31, 2019, Decision"). Except where otherwise noted, the facts recited herein are undisputed.

On January 22, 2015, petitioner presented to Dr. Breer, describing "significant recent physical symptoms which have contributed to feelings of anxiety and being overwhelmed with stress." Pet'r Ex. 7 at 1. During this appointment, petitioner stated a concern that her "ocular respiratory" symptoms were related to the influenza vaccine. *Id.* at 2.

On November 18, 2015, petitioner received the Tdap vaccine during a visit with a new primary care physician, David Preston, M.D. Pet'r Ex. 1(a) at 000073. During this visit, petitioner mentioned having a hemifacial spasm since birth and she was referred to physical therapy for "longstanding neck discomfort and limitation of range of motion." *Id.* at 000070. Petitioner did not raise concerns about any neurological symptoms, or state that she previously experienced an adverse reaction to the influenza vaccine during the visit. *Id.* at 000070-73.

On December 10, 2015, petitioner began physical therapy and stated to her physical therapist that her neck pain began five years prior without associated trauma. Pet'r Ex. 1(b) at 000039. After the completion of petitioner's physical therapy, petitioner presented to Dr. Preston, reporting that her neck pain had been alleviated, but also reporting "a new problem, in that she gets intermittent tingling and numbness of the toes of both feet." Pet'r Ex. 1(a) at 000067. Dr. Preston concluded that petitioner's symptoms were "consistent with an early sensory peripheral neuropathy" and "most consistent with the carpal tunnel syndrome." *Id.* at 000068. And so, Dr. Preston directed petitioner to wear wrist splints at night to control the symptoms. *Id.*

On March 2, 2016, petitioner reported to Dr. Preston for a follow-up visit and she reported that the tingling in her hands and, especially her feet, had worsened. *Id.* at 000064. At this time, petitioner raised a concern that these symptoms were an autoimmune response to her receipt of the Tdap vaccine on November 18, 2015. *Id.* Dr. Preston concluded that the "fluctuating nature" of petitioner's symptoms and the simultaneous experience in the hands and feet "would possibly argue against a peripheral neuropathy and more towards an anxiety reaction." *Id.* at 000065. And so, he referred petitioner to Robert Stein, M.D. for a neurology consultation. *Id.*

On April 20, 2016, petitioner presented to Dr. Stein and she reported that "[o]ne and a half hours after the flu shot [in October 2014] she developed shortness of breath and blurring of her eye site." Pet'r Ex. 5 at 1. Petitioner also reported that her symptoms alleviated within two

and one-half hours of their onset. *Id.* After receiving the influenza vaccine in 2014, and again after receiving the Tdap vaccine in 2015, petitioner reported tingling in her "feet and hands and arms and legs" that developed over the following several days. *Id.* at 1-2.

Dr. Stein assessed petitioner with paresthesias likely as the result of a peripheral neuropathic dysfunction stemming from a dependent small fiber polyneuropathy, migraine-like event, and a right hemifacial spasm. *Id.* at 4. And so, Dr. Stein concluded that the cause of petitioner's symptoms was unlikely to be multiple sclerosis ("MS"). *Id.*

On July 14, 2016, petitioner presented to Dr. Alexandra Degenhardt for a neurological consultation. Pet'r Ex. 1(b) at 000057-60. After reviewing petitioner's medical history, Dr. Degenhardt took notice of the temporal proximity between petitioner receiving the influenza and Tdap vaccines and the onset of her symptoms. *Id.* at 000057. After reviewing a MRI and conducting a physical examination, Dr. Degenhardt diagnosed petitioner with non-infectious ADEM. *Id.* at 000060.

In reaching this diagnosis, Dr. Degenhardt noted "mild cognitive and visual changes" that suggested some degree of a central nervous system ("CNS") syndrome, "[a]lthough there is very little on brain MRI to diagnose ADEM." *Id.* In this regard, Dr. Degenhardt found that petitioner's symptoms suggest some degree of peripheral nervous syndrome. *Id.* And so, Dr. Degenhardt diagnosed the presentation of the peripheral nervous syndrome symptoms such as Guillain-Barre Syndrome-like ("GBS") and linked its presentation to the Tdap and influenza vaccines. *Id.*

On August 5, 2016, petitioner followed up with Dr. Preston, who disagreed with Dr. Degenhardt's diagnosis. Pet'r Ex. 1(a) at 000059-62. Dr. Preston attributed petitioner's symptoms to an anxiety and panic disorder. *Id.* at 000061. Thereafter, petitioner underwent a MRI of her cervical spine on September 9, 2016, which found "no intrinsic cord abnormality," and she underwent an electromyography ("EMG") on that same date resulting in "an essentially normal study." *Id.* at 000036; Pet'r Ex. 1(c) at 000042-46.

On September 12, 2016, petitioner followed up with Dr. Degenhardt, who noted that petitioner identified new cranial pressure, in addition to pre-existing recurring headaches, which could produce cognitive issues. Pet'r Ex. 1(a) at 000027. Dr. Degenhardt also noted that with ADEM, it is "[v]ery atypical to have prolonged associated symptoms, however, [petitioner] has

a mildly elevated protein which is abnormal and can indicate[] inflammation." *Id.* at 000029. And so, Dr. Degenhardt ordered testing for autoimmune antibody mediated encephalopathies, which returned negative and without informative antibodies. *Id.* at 00004, 000029.

During a follow-up appointment with Dr. Degenhardt, on December 5, 2016, petitioner was again assessed with a "[p]ossible ADEM-like reaction to vaccination," following neuropsychology testing that detected a CNS issue and a lumber puncture that revealed elevated proteins. Pet. Ex. 1(a) at 000021-22. Dr. Degenhardt found the timing of the onset of petitioner's symptoms to be of particular relevance to the diagnosis. *Id.* at 000021. Given this, Dr. Degenhardt concluded that petitioner was experiencing a "rare and an atypical presentation." *Id.*

On January 12, 2017, petitioner received a second opinion from Dr. Haatem Reda regarding the ADEM diagnosis. Pet'r Ex. 1(b) at 000046. Dr. Reda observed that petitioner's "brain imaging findings . . . have been stable for at least 8 years and probably longer." *Id.* at 000044. And so, Dr. Reda concluded that "if [petitioner] does have CNS demyelinating disease, it predates the vaccination in 2014 and the symptoms she developed at the time." *Id.* Dr. Reda also concluded that the "differential diagnosis still includes prior [ADEM], though [MS] would be more likely on neuroimaging grounds." *Id.*

During a follow-up appointment with Dr. Degenhardt on February 16, 2017, Dr. Degenhardt disagreed with the conclusion of Dr. Reda that MS was more likely. Pet'r Ex. 1(a) at 000010. On June 5, 2018, Dr. Degenhardt reaffirmed her ADEM diagnosis, citing ongoing tingling in petitioner's palms and left leg as well as occasional skin reactions around the Tdap injection site. Pet'r Ex. 3 at 000006.

2. Proceedings Before The Special Master

On July 13, 2017, petitioner filed a petition under the Vaccine Act alleging that the influenza vaccine and/or the Tdap vaccine, caused her to develop ADEM. *See* generally Pet'r Pet. The Secretary submitted his Rule 4(c) report on April 23, 2018. *See generally* Resp't Report.

i. Petitioner's Submissions

On July 16, 2018, petitioner submitted seven pages of medical records from Dr. Degenhardt. *See generally* Pet'r Ex. 3. On August 21, 2018, the special master ordered petitioner to file an expert report with supporting medical literature, because the initial report by Dr. Degenhardt did not "adequately address the issue of causation." Order, dated Aug. 21, 2018 at 1. In the order, the special master directed that this report include, among other things: (1) the expert's qualifications; (2) the materials reviewed in informing the expert's opinion; (3) a summary of the pertinent medical facts; (4) an explanation of the relevant disease; (5) the expert's theory of how the vaccination can cause the disease; (6) an analysis of relevant temporal considerations; (7) an explanation of the logical sequence of cause and effect; and (8) whether a non-vaccine factor could or did contribute to petitioner's condition. *Id.* at 2-4.

On October 2, 2018, petitioner notified the special master of the fact that Dr. Degenhardt would serve as her expert in the proceedings before the special master. Pet'r Notice, dated Oct. 2, 2018. On October 2, 2018, petitioner also submitted a one-page document from Dr. Degenhardt stating that petitioner's ADEM diagnosis was based upon the presentation of petitioner as detailed in cited-to office notes. Pet'r Ex. 4. Dr. Degenhardt also stated that she did "not know if it is a[n] adjuvant in the vaccine that [petitioner] is reacting to, as it occur[r]ed after both a flu shot 10/2014 and a tetanus shot 11/2015, or if it is the actual superantigen." *Id.* But, Dr. Degenhardt found that the "clear temporal relationship" between the vaccines and petitioner's symptoms established ADEM as the most "consistent" diagnosis. *Id.*

On October 15, 2018, the special master ordered petitioner to submit an expert report that complied with the special master's August 21, 2018, Order. *See generally* Order, dated Oct. 15, 2018. On October 17, 2018, petitioner filed a final status report stating that she did not intend to submit any reports from non-treating experts. Pet'r Status Report, dated Oct. 17, 2018 at 2.

On December 12, 2018, petitioner filed a motion for a ruling on the record and she submitted five exhibits, consisting of medical records, medical literature, and an affidavit in support of that motion. *See generally* Pet'r Mot. for Ruling on the Record; Pet'r Exs. 5-10. In her motion, petitioner argued that her two submitted medical articles—*The spectrum of post-vaccination inflammatory CNS demyelinating syndromes*, by Dimitrios Karussis and Panayiota

Petrou and *Acute Disseminated Encephalomyelitis following Vaccination against Hepatitis B in a Child: A Case Report and Literature Review*, by Jun-liang Yuan, *et al.*—establish a "valid medical theory as to how vaccinations can cause an immunological inflammatory response." Pet'r Mot. for Ruling on the Record at 9; *see also* Pet'r Exs. 6, 9.

Petitioner also submitted a letter from Dr. Degenhardt, which states that vaccinations can cause ADEM and that petitioner's history of symptoms are "most consistent with recurrent symptoms of ADEM." Pet'r Ex. 8. Dr. Degenhardt's letter also states that "I have diagnosed [petitioner] with ADEM, as a reaction to her vaccinations."[2] *Id.*

ii. The Secretary's Expert Report

On March 27, 2019, the Secretary submitted an expert report by Dr. Subramaniam Sriram, a Professor of Neurology and Microbiology Immunity at Vanderbilt Medical Center and the head of the Multiple Sclerosis Clinic, and one piece of medical literature.[3] *See generally* Resp't Exs. A, C. In his expert report, Dr. Sriram opined that "the neurological symptoms suffered by [petitioner] were not related to the receipt of her flu or Tdap . . . vaccines." Resp't Ex. A at 7.

Dr. Sriram's expert report also questioned petitioner's ADEM diagnosis, because Dr. Sriram found that petitioner did not meet the criteria for ADEM. *Id.* at 5-6. In this regard, Dr. Sriram observed that the "only objective finding [with regards to petitioner's symptoms] is a mild left sided weakness of uncertain etiology." *Id.* at 5. Dr. Sriram also questioned the alleged connection between the vaccines and petitioner's symptoms. *Id.* In this regard, Dr. Sriram observed the mild left side weakness was first noted by Dr. Degenhardt in July 2016, and that the weakness was also present when Dr. Reda saw petitioner on January 19, 2017. *Id.* And so, Dr. Sriram opined that the weakness experienced by petitioner must have occurred after April 2016, which was 16 months after petitioner received the influenza vaccination and six months after she received the tetanus vaccination. *Id.*

[2] On April 24, 2019, petitioner filed a reply along with an additional affidavit and two additional exhibits in support of her motion. *See generally* Pet'r Reply to Mot. for Ruling on the Record; Pet'r 2nd Aff.; Pet'r Exs. 11, 12.

[3] Dr. Sriram holds board certifications in internal medicine and neurology. Resp't Ex. B at 1.

Dr. Sriram also opined that petitioner was not suffering from ADEM, because the MRI images of petitioner's brain, both prior to and subsequent to the vaccinations, were:

> [N]ot consistent with the diagnosis of CNS demyelinating disease, either acute (ADEM) or subacute chronic (MS). The MRI images are more likely patterns seen in patients with chronic migraine, which the patient suffered from.

Id.[4] In addition, Dr. Sriram opined that petitioner's other stated symptoms were inconsistent with ADEM. *Id.* Notably, Dr. Sriram observed that petitioner's "transient loss of vision in both eyes which lasted a few hours" following the influenza vaccination, "is inconsistent with the time line necessary for the development of an autoimmune response." *Id.* at 5-6. And so, Dr. Sriram concluded that petitioner's lack of noted change in the level of consciousness, encephalopathy, behavioral changes, or other fulfilment of other key criteria listed in the "[c]onsensus definition for ADEM" were determinate in concluding petitioner did not suffer from ADEM related to the vaccines at issue. *Id.* at 5-7.

3. The Special Master's Decision

On October 31, 2019, the special master issued a decision denying petitioner's motion for a ruling on the record. *See generally* October 31, 2019, Decision. In the decision, the special master found that petitioner failed to meet her burden of proof under Prongs 1, 2 and 3 of *Althen*. *Id.* at 15-19. And so, the special master dismissed petitioner's Vaccine Act claim for insufficient proof. *Id.* at 19.

With regards to *Althen* Prong 1, the special master determined that petitioner failed to demonstrate that either the influenza or the Tdap vaccines could cause her ADEM, because petitioner did not present a medical theory causally connecting either of the vaccines at issue to her injury. *Id.* at 15. Specifically, the special master identified two deficiencies in Dr. Degenhardt's opinion: First, the special master found that Dr. Degenhardt's assertion of a causal link between the vaccines and ADEM was "superficial," due to the lack of clarity of Dr. Degenhardt's statements regarding whether one or both of the vaccines at issue caused petitioner's ADEM. *Id.* at 16. In this regard, the special master found that Dr. Degenhardt

[4] Dr. Sriram's expert report states that "ADEM is an acute monophasaic disease, which is often fulminant in nature, occurring usually under the age of 10." Resp't Ex. A at 5.

failed to: (1) identify a discrete mechanism for how the vaccination(s) caused ADEM; (2) discuss relevant temporal considerations; and (3) cite to supporting medical literature. *Id.*

Second, the special master found that Dr. Degenhardt's qualifications as an expert were not adequately demonstrated during the proceedings before the special master. *Id.* Specifically, the special master noted the absence of a curriculum vitae, resume, or other form of documentation detailing Dr. Degenhardt's educational and professional background. *Id.* And so, the special master concluded that Dr. Degenhardt's "opinions and reports are not persuasive evidence to meet Petitioner's burden under *Althen* prong one." *Id.*

With regards to the medical literature submitted by petitioner, the special master also found that the two articles petitioner submitted to support her claim were insufficient to show causation. *Id.* Specifically, the special master observed that the Karussis and Petrou article relied upon by petitioner did not examine the viability of the hypotheses regarding how vaccines can cause ADEM. *Id.* In this regard, the special master noted that the article explicitly states that, "'despite a close temporal relation[ship] to vaccinations, there is no concrete evidence of a clear pathogenic correlation' between vaccinations and ADEM." *Id.* at 16-17 (citing Pet'r Ex. 6 at 3).

With regards to the Yuan article, which details vaccination-induced ADEM after receipt of the Hepatitis B vaccination, the special master found that this article was not instructive because petitioner failed to explain how the Hepatitis B vaccine was similar to either the influenza or Tdap vaccines, or how petitioner was similarly situated to the child involved in the case study addressed in that article. October 31, 2019, Decision at 17; *see also* Pet'r Ex. 9.

The special master similarly found that the existence of a temporal link between the timing of petitioner's vaccinations and the onset of her symptoms alone was insufficient to support a finding under *Althen* Prong 1, absent separate evidence addressing causation. October 31, 2019, Decision at 17. In this regard, the special master observed that the immediate onset of petitioner's symptoms following administration of the vaccinations was inconsistent with the Karussis and Petrou article, which states that symptoms "appear [a] few days following the immunization (mean: 14.2 days) but there are cases where the clinical presentation was delayed (more than 3 weeks or even up to 5 months post-vaccination) . . . ." *Id.*; Pet'r Ex. 6 at 1. And so, the special master concluded that the record evidence was insufficient to meet petitioner's

burden to show a medical theory causally connecting the vaccines at issue in this case to her injury. October 31, 2019, Decision at 17.

With regards to *Althen* Prong 2, the special master similarly determined that petitioner did not meet her burden to demonstrate a logical sequence of cause and effect showing that the vaccines at issue were the reason for her injury. *Id.* In making this determination, the special master rejected petitioner's argument that the evidence showing the proximity between the timing of her vaccinations and the onset of her symptoms is sufficient to satisfy *Althen* Prong 2. *Id.* Notably, the special master found that "Dr. Degenhardt's filings do not adequately explain why she believed Petitioner suffered from ADEM nor what criteria she used to diagnose Petitioner with ADEM." *Id.* The special master also observed that Dr. Degenhardt's report did not directly respond to the contrary opinions of petitioner's other physicians, Dr. Reda and Dr. Preston, or respond to Dr. Sriram's finding that petitioner did not meet the criteria for ADEM. *Id.* at 18.

Lastly, with regards to *Althen* Prong 3, the special master determined that petitioner did not demonstrate "an appropriate temporal relationship between [her] vaccines and her alleged injury." *Id.* Specifically, the special master determined that Dr. Degenhardt failed to "define[] the applicable onset window," or to address the two week time period for the onset of symptoms addressed in the Karussis and Petrou article, in light of the facts in this case regarding the immediate onset of petitioner's symptoms. *Id.*[5] And so, the special master concluded that petitioner also had not shown a proximate temporal relationship between the vaccinations at issue and her injury. *Id.* at 18-19.

Because the special master concluded that petitioner had not met her burden to show that either of the vaccines at issue caused her injury, the special master dismissed petitioner's claim for insufficient proof. *Id.* at 19.

Petitioner, alleging error, seeks review of the special master's decision. *See generally* Pet'r Mot. for Rev.; Pet'r Mem.

[5] The special master also noted that Dr. Sriram opined that "vaccine-induced ADEM would require at least seven-to-ten days" before the onset of symptoms. October 31, 2019, Decision at 18 (citing Resp't Ex. A at 6).

B. Procedural History

On November 20, 2019, petitioner filed a motion for review of the special master's October 31, 2019, Decision, and a memorandum in support thereof. *See generally* Pet'r Mot. for Rev.; Pet'r Mem. The Secretary responded to the motion for review on December 19, 2019. *See generally,* Resp't Resp. Petitioner filed a reply in support of her motion on January 6, 2020. *See generally* Pet'r Reply.

The petitioner's motion for review having been fully briefed, the Court resolves the pending motion.

III. STANDARDS FOR DECISION

A. Vaccine Act Claims

The United States Court of Federal Claims has jurisdiction to review the record of the proceedings before a special master and, upon such review, may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
>
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction . . . .

42 U.S.C. § 300aa–12(e)(2).

The special master's determinations of law are reviewed *de novo*. *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1373 (Fed. Cir. 2009). The special master's findings of fact are reviewed for clear error. *Id*. (citation omitted); *see also Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) ("We uphold the special master's findings of fact unless they are arbitrary or capricious."). The special master's discretionary rulings are reviewed for abuse of discretion. *Munn v. Sec'y of Dep't of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

In addition, a special master's findings as to the probative value of the evidence and the credibility of witnesses will not be disturbed so long as they are "supported by substantial

evidence." *Doe v. Sec'y of Health & Human Servs*., 601 F.3d 1349, 1355 (Fed. Cir. 2010); *see also Burns v. Sec'y of Dep't of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that the decision of whether to accord greater weight to contemporaneous medical records or later given testimony is "uniquely within the purview of the special master"). This "level of deference is especially apt in a case in which the medical evidence of causation is in dispute." *Hodges v. Sec'y of Dep't of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). In evaluating the reliability of evidence, a special master may "determine whether the testimony has a reliable basis in the knowledge and experience of the relevant discipline." *Terran ex rel. Terran v. Sec'y of Health & Human Srvs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999) (citations omitted) (internal edits omitted). And so, the Court will not substitute its judgment for that of the special master, "if the special master has considered all relevant factors, and has made no clear error of judgment." *Lonergan v. Sec'y of Dep't of Health & Human Servs.*, 27 Fed. Cl. 579, 580 (1993).

Under the Vaccine Act, the Court must award compensation if a petitioner proves, by a preponderance of the evidence, all of the elements set forth in 42 U.S.C. § 300aa–11(c)(1), unless there is a preponderance of evidence that the illness is due to factors unrelated to the administration of the vaccine. 42 U.S.C. § 300aa–13(a)(1). A petitioner can recover either by proving an injury listed on the Vaccine Injury Table (the "Table"), or by proving causation-in-fact. *See* 42 U.S.C. § 300aa–11(c)(1)(C); *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). And so, to receive compensation under the National Vaccine Injury Compensation Program, a petitioner must prove either that: (1) the petitioner suffered a "Table Injury" that corresponds to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) the petitioner's illnesses were actually caused by a vaccine. *See* 42 U.S.C. §§ 300aa–11(c)(1)(C)(i)-(ii), 300aa–13(a)(1)(A), 300aa–14(a); *see also Moberly v. Sec'y of Health & Human Servs*., 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1319-20 (Fed. Cir. 2006).

In Table and non-Table cases, a petitioner bears a "preponderance of the evidence" burden of proof. 42 U.S.C. § 300aa–13(a)(1)(A); *Althen*, 418 F.3d at 1278 (citing *Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)). And so, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the

burden to persuade the [judge] of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2 (brackets existing) (internal quotation omitted) (citation omitted); *see also Snowbank Enter., Inc. v. United States*, 6 Cl. Ct. 476, 486 (1984) (holding that mere conjecture or speculation is insufficient under a preponderance standard).

To establish a *prima facie* case when proceeding on a causation-in-fact or a significant aggravation theory, a petitioner must "prove, by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface*, 165 F.3d at 1352. In addition, petitioner must prove by a preponderance of the evidence: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and the injury. *Althen*, 418 F.3d at 1278. But, medical or scientific certainty is not required. *Knudsen by Knudsen v. Sec'y of Dep't of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994).

In *Althen*, the Federal Circuit addressed the three elements to prove causation-in-fact. *Althen*, 418 F.3d at 1278. The Federal Circuit has also held that all three elements "must cumulatively show that the vaccination was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm." *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006).

In addition, if a petitioner establishes a *prima facie* case, the burden shifts to the Secretary to show, by a preponderance of the evidence, that the injury was caused by a factor unrelated to the vaccine. *See* 42 U.S.C. § 300aa–13(a)(1)(B); *Shalala v. Whitecotton*, 514 U.S. 268, 270-71 (1995). But, regardless of whether the burden of proof ever shifts to the Secretary, the special master may consider the evidence presented by the Secretary in determining whether the petitioner has established a *prima facie* case. *See Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("[E]vidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question."); *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case[-]in-chief.").

B. Vaccine Rule 8

Vaccine Rule 8(d) of the Rules of the United States Court of Federal Claims ("RCFC") provides that:

> The special master may decide a case on the basis of written submissions without conducting an evidentiary hearing. Submissions may include a motion for summary judgment, in which event the procedures set forth in RCFC 56 will apply.

RCFC App. B, Rule 8(d). And so, special masters may rule on the record without conducting an evidentiary hearing in a Vaccine Act case. *See Simanski v. Sec'y of Health & Human Servs.*, 671 F.3d 1368, 1371 (Fed. Cir. 2012) (noting that "the Vaccine Rules provide that the special masters can decide cases on written submissions, including, in appropriate cases, by summary judgment"); *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020) (affirming no due process problem when the special master ruled on the record, without the consent of a party, after determining the record was comprehensive and fully developed).

IV. LEGAL ANALYSIS

In her motion for review, petitioner objects to the special master's conclusion that she did not meet her burden of proof in this Vaccine Act case due to the lack of an expert opinion. Pet'r Mem. at 2. Specifically, petitioner argues that the special master erred by refusing to consider the testimony and opinions of her treating physician, Dr. Degenhardt, and by ordering petitioner to hire an expert. *Id.* at 11-19. In addition, petitioner contends that the special master erred by not holding an evidentiary hearing in this case. *Id.* at 2. And so, petitioner requests that the Court set aside the special master's October 31, 2019, Decision, or remand this matter to the special master for further proceedings. *Id.* at 19-20.

The Secretary counters that the special master's decision to dismiss petitioner's claim for insufficient proof is supported by the record evidence and that the special master reasonably determined that petitioner failed to meet her burden of proof under Prongs 1, 2 and 3 of *Althen*. Resp't Resp. at 13-20. And so, the Secretary requests that the Court deny petitioner's motion for review and sustain the decision of the special master. *Id.* at 20.

For the reasons discussed below, the evidentiary record in this matter shows that the special master appropriately considered and reasonably weighed the opinions of Dr. Degenhardt

and applied the correct burden of proof in analyzing petitioner's claims under *Althen*. The record evidence also shows that the special master did not abuse her discretion in declining to conduct an evidentiary hearing in this matter. And so, the Court: (1) **DENIES** petitioner's motion for review and (2) **SUSTAINS** the decision of the special master.

A. The Special Master's Decision To Dismiss Petitioner's Claim For Insufficient Proof Was Reasonable And Supported By The Substantial Record Evidence

Petitioner's primary objection in this matter is that the special master erred in finding that petitioner had not meet her burden of proof under *Althen*, due to the lack of an expert opinion. Pet'r Mem. at 2. Specifically, petitioner argues that the special master refused to consider the opinions and reports of Dr. Degenhardt and erred by ordering petitioner to hire an expert. *Id*. at 11-12. The evidentiary record shows, however, that the special master appropriately considered and weighed the evidence in this case and reasonably determined that petitioner had not met her burden of proof under *Althen*. And so, the Court will not disturb the findings of the special master.

1. The Special Master Reasonably Determined That Petitioner Did Not Satisfy *Althen* Prong 1

As an initial matter, the record evidence shows that the special master adequately considered and appropriately weighed the opinions of Dr. Degenhardt regarding the alleged connection between the vaccines at issue and petitioner's ADEM diagnosis. The Court will not disturb the special master's findings regarding the probative value of Dr. Degenhardt's opinions and reports, so long as those findings are "supported by substantial evidence." *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1355 (Fed. Cir. 2010); *see also Burns v. Sec'y of Dep't of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that the decision of whether to accord greater weight to contemporaneous medical records or later given testimony is "uniquely within the purview of the special master").

In the October 31, 2019, Decision, the special master found the two opinions provided by Dr. Degenhardt to be of limited probative value, because Dr. Degenhardt's assertion of a causal link between the vaccines at issue and ADEM was "superficial." October 31, 2019, Decision at 15-16. Specifically, the special master found that Dr. Degenhardt failed to: (1) establish whether either the influenza or Tdap vaccine, or both, caused petitioner's ADEM; (2)

identify a causal mechanism for how either vaccine, or both vaccines, cause ADEM; (3) discuss relevant temporal considerations; (4) cite to supporting medical literature; and (5) provide her qualifications to opine on the issue of causation as an expert witness. *Id.* at 16. The special master also found that Dr. Degenhardt's qualifications as an expert were not adequately demonstrated during the proceedings before the special master, due to the absence of a curriculum vitae, resume, or other form of documentation detailing Dr. Degenhardt's educational and professional background. *Id.* And so, the special master concluded that Dr. Degenhardt's "opinions and reports are not persuasive evidence to meet Petitioner's burden under *Althen* prong one." *Id*.

The special master's decision to afford limited weight to Dr. Degenhardt's opinions is supported by the substantial record evidence. A careful review of Dr. Degenhardt's two opinions shows that Dr. Degenhardt did not explain whether she believed that the influenza or Tdap vaccine—or both vaccines—caused petitioner's ADEM. *See* Pet'r Exs. 4, 8. As the special master correctly observed in the October 31, 2019, Decision, Dr. Degenhardt's two opinions also do not address a mechanism for how either vaccine—or a combination thereof—could cause ADEM. October 31, 2019, Decision at 16. In fact, Dr. Degenhardt acknowledges in her first opinion that:

> I do not know if it is a[n] adjuvant in the vaccine that [petitioner] is reacting to, as it occur[r]ed after a flu shot 10/2014 and tetanus shot 11/2015, or if it is the actual superantigen. However, there is a clear temporal relationship between the vaccinations and her symptoms, and so the most consistent diagnosis is ADEM.

Pet'r Ex. 4. Dr. Degenhardt's second opinion is similarly lacking with regards to establishing a medical theory of causation, because this opinion simply states "[a]s is commonly known in medicine and public health, vaccinations can cause [ADEM]." Pet'r Ex. 8.

The record evidence also supports the special master's determination that Dr. Degenhardt failed to discuss relevant temporal considerations with regards to petitioner's medical theory of causation. As the special master observed in the October 31, 2019 Decision, Dr. Degenhardt "did not discuss what an appropriate temporal relationship would be for the flu or Tdap vaccines to be linked to the development of ADEM" in either of her opinions. October 31, 2019, Decision at 16; *see also* Pet'r Exs. 4, 8. The special master also correctly observed

that Dr. Degenhardt failed to cite to any supporting medical literature to substantiate the view that the vaccines at issue caused petitioner's ADEM. *Id.*[6] Given this, the substantial evidence in the record supports the special master's determination that Dr. Degenhardt's opinions and reports were not persuasive evidence to meet petitioner's burden under *Althen* Prong 1.[7] October 31, 2019, Decision at 16.

The special master also reasonably concluded that the medical literature submitted by petitioner did not advance a reliable medical theory of causation in this case. *See* October 31, 2019, Decision at 16-17. In the October 31, 2019, Decision, the special master correctly observed that the Karussis and Petrou article upon which petitioner relies does not establish causation, because this article fails to examine the viability of the hypotheses of how the vaccines at issue can cause ADEM. *Id.*; Pet'r Ex. 6 at 2-3. The special master also correctly observed that the Yuan article, upon which petitioner also relies, was unhelpful, because neither petitioner nor the article explain how the Hepatitis B vaccine is like the influenza and/or Tdap vaccines, or how petitioner, who is an adult, is similarly situated to the child addressed in that article. October 31, 2019, Decision at 16-17; *see also* Pet'r Ex. 9.[8]

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[6] Petitioner's reliance upon *Capizzano v. Sec'y of Health & Human Servs.*, to establish a medical theory of causation is also misplaced. Pet'r Mem. at 9-10, 12. *Capizzano* addresses the weight afforded to the opinion of a treating physician in satisfying *Althen* Prong 2. *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006).

[7] The Court is also not persuaded by petitioner's argument that the special master failed to properly consider and weigh the temporal evidence in this case. Pet'r Mem. at 15-17. In the October 31, 2019, Decision, the special master found that the evidence that petitioner offered to show that her symptoms occurred immediately after receiving the influenza and Tdap vaccines was not alone sufficient to establish causation. October 31, 2019, Decision at 17. The Federal Circuit has long held that "a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury." *Grant v. Sec'y of Dep't of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). And so, the special master appropriately concluded that petitioner had not established a causal link between the influenza and Tdap vaccines and her injury.

[8] Petitioner's reliance upon *Mondello v. Sec'y of Dep't of Health & Human Servs.*, to argue that the special master erred by affording limited weight to Dr. Degenhardt's opinions, is also misplaced. Pet'r Mem. at 18-19; *Mondello v. Sec'y of Dep't of Health & Human Servs.*, 132 Fed. Cl. 316 (2017). In *Mondello*, the Court reversed the special master's decision to deny a vaccine injury claim because, "[b]y emphasizing the fact that petitioner did not submit an outside expert opinion and by not taking account of the relevant medical and scientific literature, the Special Master impermissibly raised petitioner's burden of providing a medical theory beyond that of biological plausibility . . . ." *Mondello*, 132 Fed. Cl. at 321. But, in this case, there is no evidence that the special master relied upon the fact that petitioner did not have an outside expert, or that the special master ignored the relevant medical and

Because the evidentiary record makes clear that the special master appropriately considered and weighed the opinions and reports of Dr. Degenhardt—and the other evidence submitted by the parties in this case—in analyzing petitioner's Vaccine Act claim, petitioner has not shown that the special master erred by concluding that petitioner failed to meet her burden of proof under *Althen* Prong 1.

2. The Special Master Reasonably Determined That Petitioner Failed To Satisfy *Althen* Prong 2

The record evidence similarly shows that the special master reasonably concluded that petitioner failed to prove a logical sequence of cause and effect showing that the influenza and/or Tdap vaccines were the reason for her injury. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (stating that, to satisfy *Althen* Prong 2, petitioner must prove by preponderant evidence "a logical sequence of cause and effect showing that the vaccination was the reason for the injury"). In the October 31, 2019, Decision, the special master rejected petitioner's argument that evidence showing a proximate temporal relationship between her receipt of the influenza and Tdap vaccines and the onset of symptoms was sufficient to satisfy *Althen* Prong 2. October 31, 2019, Decision at 17-18. The special master also found that the totality of the evidence in this case did not establish that petitioner suffers from ADEM, because "Dr. Degenhardt's filings do not adequately explain why she believed Petitioner suffered from ADEM nor what criteria she used to diagnose Petitioner with ADEM." *Id.* at 17.

In this regard, the special master observed that Dr. Degenhardt's opinions and reports do not directly respond to the contrary opinions of petitioner's other treating physicians, Dr. Reda and Dr. Preston, and the expert opinion of Dr. Sriram, regarding petitioner's ADEM diagnosis. *Id.* at 18. And so, the special master concluded that petitioner failed to meet her burden under *Althen* Prong 2. *Id.*

The special master's conclusion is supported by the evidentiary record. As discussed above, the special master correctly concluded that the evidence showing a proximate temporal relationship between petitioner's receipt of the influenza and Tdap vaccines and the onset of her

scientific literature, in reaching her decision to dismiss petitioner's claim for insufficient proof. *See generally* October 31, 2019, Decision.

symptoms was insufficient to meet her burden of proof in this case. *See Grant v. Sec'y of Dep't of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (holding that "a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury").

The special master also reasonably concluded that Dr. Degenhardt's ADEM diagnosis lacks support, when considered in light of the totality of the evidentiary record in this case. October 31, 2019, Decision at 18. In this regard, a careful review of Dr. Degenhardt's two opinions reveals that Dr. Degenhardt failed to state the diagnostic criteria that she employed in diagnosing petitioner with ADEM, or to explain how this diagnosis was made without a prior finding that petitioner had developed an encephalopathy—a requirement for an ADEM diagnosis. Pet'r Exs. 4, 8. It is also noteworthy that petitioner's other treating physicians, Dr. Preston and Dr. Reda, both disagree with Dr. Degenhardt's ADEM diagnosis. Pet'r Ex. 1(a) at 000065 (finding that petitioner's symptoms were related to her anxiety problems); Pet'r Ex. 1(b) at 000044 (finding that petitioner was more likely to have MS). During the proceedings before the special master, Dr. Sriram also opined that petitioner's symptoms and neuroimaging results are inconsistent with an ADEM diagnosis. Resp't Ex. A at 5. Given the substantial evidence calling into question petitioner's ADEM diagnosis, the special master reasonably concluded that petitioner had not met her burden under *Althen* Prong 2.

3. The Special Master Reasonably Determined That Petitioner Failed To Satisfy *Althen* Prong 3

Lastly, the record evidence also makes clear that the special master reasonably concluded that petitioner failed to prove an appropriate, proximate temporal relationship between the two vaccines at issue and her injury. *Althen*, 418 F.3d at 1278 (stating that, under *Althen* Prong 3, petitioner must prove by preponderant evidence "a showing of a proximate temporal relationship between the vaccination and the injury"). In the October 31, 2019, Decision, the special master determined that petitioner did not demonstrate "an appropriate temporal relationship between [her] vaccines and her alleged injury," because Dr. Degenhardt did not "define[] the applicable onset window," or address how to reconcile the two-week onset time period discussed in the Karussis and Petrou article with evidence regarding the immediate onset of petitioner's symptoms in this case. October 31, 2019, Decision at 18; *see also* Pet'r Ex. 6 at 2 (stating that "[u]sually the symptoms . . . appear [a] few days following the immunization

(mean: 14.2 days[]) but there are cases in which the clinical presentation was delayed (more than 3 weeks or even up to 5 months post-vaccination)"). As discussed above, Dr. Sriram also opined in his expert report that vaccine-induced ADEM would require at least seven-to-ten days before the onset of symptoms—such an onset window would be several days after the timing of the onset of symptoms alleged by petitioner in this case. Resp't Ex. A at 6. And so, the special master concluded that petitioner had not shown a proximate temporal relationship between the vaccinations at issue and her injury.

The record evidence supports the findings of the special master. A review of Dr. Degenhardt's two opinions shows that Dr. Degenhardt failed to identify either a specific time period for the onset of petitioner's symptoms or to show a link between the vaccines and petitioner's ADEM. *See generally* Pet'r Exs. 4, 8. Petitioner also has not addressed or reconciled the difference between the two-week onset window identified in the Karussis and Petrou article and the immediate onset of symptoms following the vaccinations in this case. *See* Pet'r Mem. at 8-19 (showing that petitioner does not address this difference).[9] Nor has petitioner addressed or challenged Dr. Sriram's expert opinion, that the onset of petitioner's symptoms should have occurred within 7-10 days after receiving the vaccines. *Id*. Given this, the special master reasonably concluded that petitioner failed to satisfy her burden under *Althen* Prong 3.

B. The Special Master Did Not Err By Declining To Conduct A Hearing

As a final matter, petitioner's objection to the special master's decision not to hold an evidentiary hearing in this matter is unpersuasive. Pursuant to Vaccine Rule 8(d), "the special master may decide a case on the basis of written submissions without conducting an evidentiary hearing." RCFC App. B, Rule 8(d); *see also Simanski v. Sec'y of Health & Human Servs.*, 671 F.3d 1368, 1371 (Fed. Cir. 2012) (noting that "the Vaccine Rules provide that the special masters can decide cases on written submissions, including, in appropriate cases, by summary judgment"); *Kreizenbeck v. Sec'y of Health & Human Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020) (affirming no due process problem when the special master ruled on the record, without

[9] The Karussis and Petrou article does not identify any instance of influenza vaccine-induced symptoms that occur earlier than four days after receipt of the vaccine, nor any instance of tetanus vaccine-induced symptoms that occur earlier than 15 days after receipt of the vaccine. Pet'r Ex. 6 at 4-5 (Table 2).

the consent of a party, after determining the record was comprehensive and fully developed). The Court reviews the special master's decision regarding whether to conduct an evidentiary hearing in this case for abuse of discretion. *Munn v. Sec'y of Dep't of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

The evidentiary record in this case makes clear that the special master did not abuse her discretion in declining to hold an evidentiary hearing. It is undisputed that petitioner filed a motion for a ruling on the record, based upon the medical records, medical literature, opinions of Dr. Degenhardt and an affidavit that petitioner submitted to support her claim. *See generally* Pet'r Mot. for Ruling on the Record; Pet'r Aff.; *see also* Pet'r Exs. 5-10. While petitioner may have preferred that the special master had conducted an evidentiary hearing before resolving this case, she acknowledges that the special was under no obligation to do so in this case. Pet'r Mot. for Ruling on the Record at 1.

The special master's decision not to conduct an evidentiary hearing was reasonable. As discussed above, the record evidence in this case also shows that the special master carefully and appropriately considered all of the evidence submitted by the parties before ruling on petitioner's motion for a ruling on the record. In fact, the special master allowed petitioner to submit an additional affidavit and medical records in support of her claim, after petitioner filed her motion for a ruling on the record. *See generally* Pet'r 2nd Aff.; *see also* Pet'r Exs. 11, 12. The record evidence also shows that petitioner did not provide sufficient evidentiary support for her claim that the influenza and/or Tdap vaccines caused her alleged ADEM. Given this, the Court declines to disturb the decisions of the special master.

Because the evidentiary record in this matter shows that the special master appropriately weighed the evidence, reasonably concluded that petitioner failed to meet her burden of proof under Prongs 1, 2 and 3 of *Althen* and provided a rational basis for dismissing this matter for insufficient proof, the Court will not set aside the sound determination of the special master.

V. CONCLUSION

In sum, petitioner has not shown that the special master erred in considering and weighing the opinions of Dr. Degenhardt, or that the special master applied an incorrect burden of proof in analyzing petitioner's claims under *Althen*. Petitioner has also not shown that the

special master abused her discretion in declining to conduct an evidentiary hearing in this matter. And so, for these reasons, the Court:

1. **DENIES** petitioner's motion for review of the special master's October 31, 2019, Decision; and

2. **SUSTAINS** the decision of the special master.

The Clerk is directed to enter judgment accordingly.

Some of the information contained in this Memorandum Opinion and Order may be considered privileged, confidential or sensitive personally-identifiable information that should be protected from disclosure. And so, this Memorandum Opinion and Order shall be **FILED UNDER SEAL**. The parties shall review the Memorandum Opinion and Order to determine whether, in their view, any information should be redacted prior to publication. The parties shall also **FILE**, by **April 20, 2020,** a joint status report identifying the information, if any, that they contend should be redacted, together with an explanation of the basis for each proposed redaction.

IT IS SO ORDERED.

s/Lydia Kay Griggsby
LYDIA KAY GRIGGSBY
Judge